

REMARKS

In response to the above-identified Office Action, Applicant seeks reconsideration in view of the following remarks. In this response, Applicant does cancel any claims. Applicant adds claim 23. Applicant amends claims 1 and 5. Accordingly, claims 1-3, 5, 7, 21, 22 and 23 are pending.

I. Claims Rejected Under 35 U.S.C. § 101/112, first paragraph

Claims 1, 2, 3, 5, 7, 21 and 22 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter which is not described in the specification in such a way as to convey to one skilled in the art that the inventor at the time the application was filed had possession of the claimed invention. Applicant respectfully disagrees for the following reasons.

The Examiner bears the burden of proof in establishing a *prima facie* case to support a rejection based on the written description requirement. Specifically, "the Examiner has the initial burden of presenting evidence for reasons why a person skilled in the art would not recognize in [the] specification disclosure a description of the invention defined by the claims." See, *Ex parte Sorenson*, 3 USPQ2d 1462, 1463 (B.P.A.I. 1987). The Examiner argues that the limitations of "a base comprising at least 20 percent by weight of moisturizer" and a plurality of particles suspended in a base "having an average particle size from 34 to 124 microns" found in claims 1 and 5, respectively, are not present in the disclosure of the specification. Applicant notes that the specification clearly defines ranges for both the average particle size and the percentage by weight of a moisturizer for a compound. As previously noted in a prior response, the specification describes an embodiment where "the abrasive particles or microcrystals of corundum having average particle size on the order of 34 μm to 556 μm (320 to 30 grit)." See paragraph 12. Similarly, the specification explicitly describes in paragraph 16, an embodiment where a composition is "20 to 70 percent out of gel." Claim 1 has been amended to recite "at least about twenty three percent by weight a moisturizer." Further, the specification provides an embodiment

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where the ingredients include at least 29.3 percent moisturizer (see page 5, octyl palmitate, safflower oil, and propylene glycol).

The Examiner has not established why these passages of the specification do not support the language of claim limitations in claims 1 and 5. The Examiner sets forth in the present Office Action a number of arguments, each of which is inapposite, or fails to support a *prima facie* case of insufficient support in the written description. The Examiner again cites *In re Lukach* 169 USPQ 795 (CCPA 1971) for the holding that a subgenus range was not supported by a generic disclosure and a specific example within a subgenus range and *In re Smith*, 173 USPQ 679, 683 (CCPA 1972) for the proposition that a subgenus is not necessarily described by a genus encompassing it and species upon which it reads.

In re Wertheim (I) 191 USPQ 90 (CCPA 1976) is directly relevant to the discussion at hand and the determination as to whether these elements of claims 1 and 5 meet the written description requirement. *In re Wertheim (I)* is a precedent subsequent in time to both *In re Lukach* and *In re Smith*. *In re Wertheim (I)* directly addresses the holdings of both of these cases and provides a guiding discussion of the manner in which a written description requirement should be determined. See *In re Wertheim (I)* at 96. As noted by the Court, in *In re Wertheim (I)*, *In re Lukach* appropriately sets forth the proposition that "the invention claimed did not have to be described in *ipsis verbis* in order to satisfy the description requirement of section 112." See *In re Lukach* at 796. *In re Lukach*, *In re Smith*, and *In re Wertheim (I)* all clearly set forth that the manner in which a written description requirement should be analyzed on a case by case basis with close attention to the facts of the case to determine whether an application conveys to those skilled in the art information that this Applicant invented the subject matter of the claims. See *In re Smith* at 683 ("precisely how this description must come to comply with section 112 must be left to case by case development") and *In re Wertheim (I)* at 97 ("mere comparison of ranges is not enough, nor are mechanical rules a substitute for the analysis of each case on its facts to determine whether an application conveys to those skilled in the art the information that the applicant invented the subject matter of the claims").

In this regard, all these cases clearly refute the analysis utilized in *In re Rodman* 106 USPQ 142 (CCPA 1955) which the Examiner relies upon in arguing that it is prohibited to arbitrarily choose a number. See *In re Wertheim* at 97 ("Broadly articulated rules are particularly inappropriate in this area.") citing as an example in *In re Smith* for support. Further, the Examiner's position that it is not permissible for an Applicant to amend claims in order to avoid prior art subject matter where the elements are not explicitly disclosed in the specification is clearly erroneous. Applicant reproduces below the Court's discussion of exactly this matter in *In re Wertheim* at 98:

"If lack of literal support alone were enough to support a rejection under § 112, then the statement of *In re Lukach*, supra, 58 CCPA at 1235, 442 F.2d at 969, 169 USPQ at 796 that 'the invention claimed does not have to be described in *ipsis verbis* in order to satisfy the description requirement of § 112,' is empty verbiage. The burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in *ipsis verbis* is insufficient."

Further, the Court states:

"In other words, we must decide whether the invention appellants seek to protect by their claims is part of the invention that Appellants have described as theirs in the specification. That what appellants claim as patentable to them *is less* than what they describe as the invention is not conclusive if their specification also reasonably describes that which they do claim. Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. As we said in a different context in *In re Saunders*, 58 CCPA 1316, 1327, 444 Fd 599, 607, 170 USPQ 213, 220 (1971):

To rule otherwise would let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species mainly because he erroneously thought he was first with the genus when he filed . . . Since the patent law provides for the amendment during prosecution of *claims*, as well as the specification supporting claims, 35 U.S.C. 132, it is clear that the reference to "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention" in the second paragraph of 35 USC 112 does not prohibit the applicant from changing what he "regards as his invention" . . . during the pendency of his application."

See *In re Wertheim* at 97.

In regard to the arguments set forth by the Examiner on page 3 based on *In re Wertheim (II)*, 209 USPQ 554 (CCPA 1981). Applicant has reviewed the holding of this case and believes the Examiner's arguments based upon *In re Wertheim (II)* are wholly inapposite. A discussion on page 565, in *In re Wertheim* discusses the presence of a potential prior art reference that had several continuation in parts having anticipatory matter and the priority date of that anticipatory matter. This is a wholly different discussion from the analysis of the satisfaction of the written description requirement. Applicant also notes that the Examiner's discussion of this case is inaccurate and that the Court makes no statement, much less a holding, that the Applicant for the Wertheim patent amended claims to avoid prior art subject matter that fell within the scope of the broad disclosure in the parent case and therefore constituted new matter. As Applicant noted, the discussion of the Court in *In re Wertheim* is related to anticipatory references and Applicant further notes that the Court reversed the rejection of the claims of the Wertheim patent under discussion. Thus, *In re Wertheim (II)* has little relevance as to whether claims 1 and 5 meet the written description requirement.

The Examiner's statement that the ruling in *In re Wertheim (I)* is based on the fact that there was specific embodiment of 36 percent and the minimum of the claimed range was 35 percent is simply inaccurate. In fact, the claims in *In re Wertheim (I)* specifically claims 2, 37 and 38 claimed a range of between 35 percent and 60 percent which was supported by a broad range in the description of 25 percent to 60 percent. See *In re Wertheim* at 98 ("claims 2, 37, and 38 which claim a solids content range of 'between 35 percent and 60,' present a different question. They clearly claim a range within the described broad range of 25 percent to 60 percent solids; the question is whether, *on the facts* the PTO has presented sufficient reason to doubt the broader described range also describes the somewhat narrower claimed range. We note that there is no evidence, and the PTO does not contend otherwise, that there is in fact any distinction, in terms of operability of Appellant's process or of the achievement of any desired result between the claimed lower limit of solids content and that disclosed in the Swiss application.") Thus, the facts in *In re Wertheim* are directly analogous to the facts of the present case where the Applicant claimed ranges

that fall directly within broader ranges described in the specification. Further, the narrow ranges in the present application have the same ability to produce the same desired results as the broader range in contrast to the fact scenario of *In re Lukach*, which the Examiner cites against the present application where the Applicant relies on a single example ratio of 2.6 in the specification to support a claim to a range of ratios between 2.0 and 3.0. See *In re Lukach* at 797. Thus, the proper analysis in this case is to look closely at the actual circumstances of the description in relation to the claims to determine if one of ordinary skill in the art would understand that the Applicant possessed the invention at the time of filing. In this regard, the case of *In re Wertheim (I)* is directly on point with the facts of the instant application. And thus for the same reasons set forth by the Court in *In re Wertheim (I)*, claims 1 and 5 meet the written description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, reconsideration and withdrawal of the written description requirement rejection are requested.

In regard to claims 2-7, 21 and 22, these claims depend from independent claims 1 and 5 and incorporate the limitations of claims 1 and 5 objected to by the Examiner. Thus, at least for the reasons mentioned above in regard to claims 1 and 5, these claims also meet the written description requirement.

Claim 21 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim subject matter which Applicant regards as the invention.

The Examiner asserts that claim 21 claims a product or composition of matter and the method steps of using the product. Applicant respectfully disagrees. The language of claim 21 "when the composition may be left on the skin after application" describes a property of the composition." This language is not in the form of a step or method which begins with a gerund such as 'leaving the composition on the skin after application.' Thus, the claimed language is in the form of a description of the properties of the composition which allow it to be left on the skin after application to the skin. Therefore, the language of claim 21 particularly points out the subject matter which the Applicant regards as the invention.

Claim 21 stands rejected under 35 U.S.C. § 101 as being directed to neither a process nor a composition of matter, but rather the claim overlaps the two statutory classes. Applicant respectfully disagrees. As mentioned above in regard to the rejection of claim 21 under 35 U.S.C. § 112, second paragraph, Applicant believes that the claim language is not in the format of a method or step. Rather, the claim language clearly describes a characteristic of the composition. Thus, the claim is directed to a single statutory class of invention. Accordingly, reconsideration and withdrawal of the 35 U.S.C. § 101 rejection of claim 21 are requested.

II. Claims Rejected Under 35 U.S.C. § 102/103

Claims 1-3, 5, 7, 21 and 22 are rejected under 35 U.S.C. § 102(e) as anticipated by or in the alternative under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 6,290,976 issued to Messenger (hereinafter "Messenger").

Applicant believes Messenger is not a valid prior art reference based on the new Declaration submitted herewith under 37 C.F.R. §1.131. Applicant establishes therein that the present invention as claimed in claims 1-3, 5, 7, 21 and 22 was reduced to practice at least as early as the filing date of Messenger, April 6, 2000. A new exhibit is provided in support of the declaration. The declaration explains facts that Applicant relies on to establish prior invention. The accompanying exhibit shows an actual formulation of the claimed invention. Therefore, Applicant respectfully requests that the anticipation and obviousness rejection of claims 1-3, 5, 7, 21 and 22 based on Messenger be reconsidered and withdrawn.

Claims 1, 2, 21 and 22 stand rejected under 35 U.S.C. § 102(b) as anticipated by or in the alternative under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,294,179 issued Lee, et al. (hereinafter "Lee").

To establish a *prima facie* case of obviousness, the Examiner must show that the cited reference teaches or suggests each of the elements of a claim. It is axiomatic that to anticipate a claim, a single reference must teach each element of the claims. In regard to claim 1, this claim includes the element of "a base comprising at least about twenty three percent by weight and moisturizer." The Examiner argues that Lee teaches these elements of claim 1 because Lee includes

water in amount greater than 20 percent. Applicant believes that the Examiner's characterization of water as a moisturizer is contrary to the common usage of the term 'moisturizer' by those of ordinary skill in the art. The Examiner's cites the definition provided by the American Heritage Dictionary of "a cosmetic lotion or cream applied to the skin to counter dryness" as his interpretation of moisturizer in claim 1. The Examiner noted that claim 1 also included the elements of a moisturizer being twenty percent of the base. Claim 1 now recites a moisturizer that is "at least about twenty three percent by weight moisturizer." The Examiner relies on the water content of Lee as teaching this element of claim 1. The Examiner states that "water clearly provides moisture and is present in an amount greater than 20 percent." However, Applicant believes that the Examiner's reliance on the water content of Lee does not teach or suggest a moisturizer that is twenty percent of a base. The Examiner's own definition of moisturizer is a cosmetic lotion or cream that counters dryness. One of ordinary skill in the art would understand that water does not meet this definition. Water is neither a lotion nor a cream and does not itself moisturize the skin. Applicant believes that the Examiner incorrectly states that "water clearly provides moisture." Rather, water is moisture. One of ordinary skill in the art would understand that a moisturizer is able to counter the dryness skin by controlling water by either attracting moisture to a top layer of skin or reducing water loss by creating a barrier. See the definition of a moisturizer provided by the Applicant in paragraph 14 of the application. Thus, in this regard, the Applicant has provided a definition for moisturizer that is sufficiently clear in the specification to be understood by one of ordinary skill in the art. See MPEP § 2111, entitled "Applicant May be Own Lexicographer." Thus, the Examiner has not established that Lee teaches or suggests a moisturizer that is twenty three percent of the base. Therefore, the Examiner has not established that Lee teaches or suggests each of the elements of independent claim 1. Therefore, the Examiner has not established anticipation or a *prima facie* case of obviousness for claim 1 over Lee. Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 1 are requested.

In regard to claims 2, 21, and 22, these claims depend from independent claim 1 and incorporate the limitations thereof. Thus, at least for the reasons mentioned above in regard to

independent claim 1, these claims are not obvious over Lee. Accordingly, reconsideration and withdrawal of the anticipation and obviousness rejections of these claims are requested.

Further, in regard to claim 21, this claim includes the element of "where the composition may be left on the skin after application." The Examiner argues that this is an intended use. Applicant disagrees. Language of the claim describes a property of the composition. The property of the composition is analogous to describing the composition as being non-toxic. Thus, the Examiner bears the burden of showing that the cited references teach this element of the claim. The Examiner has not indicated and Applicant has been unable to discern any part of Lee that teaches this element of claim 21. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness for the dependent claims 2, 21 and 22. Accordingly, reconsideration and withdrawal of the obviousness rejection of these claims are requested.

Claims 1-3, 21 and 22 stand rejected under 35 U.S.C. § 102 as anticipated by or in the alternative under 35 U.S.C. § 103 as obvious over U.S. Patent No. 3,092,111 issued to Saperstein (hereinafter "Saperstein") or U.S. Patent No. 4,957,747 issued to Stiefel (hereinafter "Stiefel"). Applicant respectfully disagrees for the following reasons. As discussed above in regard to Lee, independent claim 1 includes the element of a base that is at least about twenty three percent by weight a moisturizer. In rejecting claim 1 over both Saperstein and Stiefel, the Examiner relies on water as being a moisturizer in an amount greater than 20 percent of a base. For the reasons set forth above, the term moisturizer as recited in claim 1 is not taught or suggested by water. Thus, the Examiner has failed to establish that Saperstein and Stiefel teaches or suggest each of the elements of claim 1. Accordingly, reconsideration and withdrawal of the anticipation and obviousness rejections of claim 1 are requested. Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 1 are requested.

In regard to claims 2, 3, 21 and 22, these claims depend from independent claim 1 and incorporate the limitations thereof. Thus, at least for the reasons mentioned above in regard to independent claim 1, these claims are not taught or suggested by Saperstein or Stiefel. Also, in regard to claim 21, the Examiner has not set forth wherein either Saperstein or Stiefel teach a

composition with a property of being able to be left on skin after application. As set forth above, this element is a property of the composition not an intended use. Therefore, the Examiner has failed to establish anticipation or a *prima facie* case of obviousness for claims 2, 3, 21 and 22. Accordingly, reconsideration and withdrawal of the obviousness rejection of these claims are requested.

Claims 1-3, 5, 7, 21 and 22 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,284,533 issued to Imamura (hereinafter "Imamura"). Applicant respectfully disagrees for the following reasons.

In regard to independent claim 1, this claim includes the elements of "a base comprising at least about twenty three percent by weight a moisturizer." As discussed above in regard to Lee, water is not a moisturizer as recited in the claims. Again, the Examiner relies on water being twenty percent of the composition to teach the elements of independent claim 1. Thus, for the reasons mentioned above in regard to Lee, the use of water in Imamura does not teach or suggest each of the elements of independent claim 1. Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 1 are requested.

In regard to claims 2, 3, 21 and 22, these claims depend from independent claim 1 and incorporate the limitations thereof. Thus, at least for the reasons mentioned above in regard to independent claim 1, these claims are not obvious over Imamura. Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 2, 3, 21 and 22 are requested.

In regard to claim 5, this claim includes the elements of "a base in the form of a cream suitable for application to the human skin." As the Examiner has acknowledged, Imamura teaches a compound with a viscosity of less than 5000 cps. Applicant submits the previously cited article titled "Topical Drug Bioequivalence: FDA Revised Strategy to be Presented to Committee; Reporting CMC Changes Also on Agenda." Applicant also notes the definition of the cream provided by cosmetic ingredients glossary at www.corycosmetics.com/cosmetic_ingredients_glossary.htm which defines a cream as "a preparation for the skin used to impart moisture. A cream is usually thicker and more emollient

'smoother and softer' than a lotion. "When interpreting claims, words are given their plain meaning. See MPEP § 2111.01. The above references are cited to establish what the plain meaning of the term cream means in terms of defining the viscosity of the cream. The definition applied by the cosmetic glossary clearly shows that one of ordinary skill in the art would understand the viscosity of a cream as greater than that of a lotion. The article related to the proposed FDA guidelines clearly establishes that one of ordinary skill in the art would understand that a cream typically has a viscosity greater than 30,000 cps while a lotion has a viscosity below 30,000 cps.

The patent cited by the Examiner (U.S. Patent No. 6,284,257) discusses a compound having a viscosity between 600 and 1000 cps. Applicant asserts that defining this compound as a cream would be contrary to the common usage of the term used by those of ordinary skill in the art. Defining a compound having a viscosity of 600 to 1000 cps as a cream places the substance in the same category as pure motor oil. See the attached article on viscosity from liquidcontrol.com. One of ordinary skill in the art would understand that both lotion and creams have a viscosity greater than an oil. Thus, each of the above mentioned references support the Applicant's assertion that a conventional cream would have a viscosity greater than 30,000 cps and that the Examiner's cited reference uses a definition of a cream that is non-standard and would not be the definition of a cream utilized by one of ordinary skill in the art. Thus, the Examiner has given a meaning to the word cream other than that which is the plain meaning of the word when considered in light of the relative viscosities of oils, lotions and creams as understood by those of ordinary skill in the art. Therefore, Imamura does not teach or suggest a base in the form of a cream as recited in claim 5. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness for claim 5. Accordingly, reconsideration and withdrawal of the anticipation and obviousness rejections of claim 5 are requested.

In regard to claim 7, this claim depends from independent claim 5 and incorporate the limitations thereof. Thus, at least for the reasons mentioned above in regard to independent claim

5, claim 7 is not anticipated by or obvious over Imamura. Accordingly, reconsideration and withdrawal of the anticipation and obviousness rejections of claim 5 are requested.

Claims 5 and 7 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent Application No. 2002/0090385 applied for by Fox, et al. (hereinafter "Fox").

Applicant has submitted herewith a new rule 131 affidavit which Applicant believes satisfies the requirements of 37 C.F.R. 1.131(b). Thus, Fox is not prior art to the present application. Accordingly, reconsideration and withdrawal of the obviousness rejection of claims 5 and 7 over Fox are requested.

Claims 1-3, 5, 7, 21 and 22 stand rejected under 35 U.S.C. § 102 as anticipated by or in the alternative under 35 U.S.C. § 103 as obvious over U.S. Patent No. 5,219,571 issued to Wise, (hereinafter "Wise"). Applicant respectfully disagrees for the following reasons.

In regard to claim 1, this claim includes the elements of a base comprising at least about twenty three percent by weight a moisturizer. The Examiner has not indicated what aspect of Wise teaches these elements of claim 1. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness for independent claim 1. Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 1 are requested.

In regard to claims 2, 3, 21 and 22, these claims depend from independent claim 1 and incorporate the limitations thereof. Thus, at least for the reasons mentioned above in regard to independent claim 1, these claims are not obvious over Wise.

In regard to claim 5, this claim includes the element of a "base in the form of a cream suitable for application to human skin." The Examiner has not cited and the Applicant has been unable to discern any part of Wise that teaches a base in the form of a cream. The Examiner argues that Wise discloses a lipophilic carrier that may be USP cold cream. However, a base taught by Wise also includes alcohol that controls the viscosity of the product. See col. 3, lines 35-37 of Wise. The Examiner has not indicated and Applicant has been unable to discern any part of Wise that teaches that the resulting combination of alcohol with the lipophilic carrier which form the base in which particles are suspended is a cream. Rather, the specification of Wise indicates that a low

viscosity base is desired. See col. 3, lines 18-21 of Wise. Therefore, the Examiner has failed to establish that Wise teaches or suggests each of the elements of claim 5. Accordingly, reconsideration and withdrawal of the anticipation and obviousness rejection of claim 5 are requested.

In regard to claim 7, this claim depends from independent claim 5 and incorporate the limitations thereof. Thus, at least for the reasons mentioned above in regard to independent claim 5, Wise does not teach or suggest the elements of the claim 7. Accordingly, reconsideration and withdrawal of the anticipation and obviousness rejections of claim 7 are requested.

Claims 1-3, 5, 7, 21 and 22 stand rejected under 35 U.S.C. § 103 as obvious over U.S. Patent No. 5,607,980 issued to McAtee, et al. (hereinafter "McAtee").

In regard to claim 1, this claim includes the elements of a base that is at least about twenty three percent by weight a moisturizer. McAtee does not teach these elements of the claim. Rather, McAtee teaches a moisturizer that may be "at a level from about 0.1 percent to about 20 percent of a composition." Thus, McAtee does not teach or suggest a moisturizer that is greater than about twenty three percent of a base. Therefore, McAtee does not teach or suggest each of the elements of claim 1. Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 1 are requested.

In regard to claims 2, 3, 21 and 22, these claims depend from independent claim and incorporate the limitations thereof. Thus, at least for the reasons mentioned above in regard to independent claim 1, these claims are not obvious over McAtee. Accordingly, reconsideration and withdrawal of the obviousness rejection of claims 2, 3, 21, and 22 are requested.

In regard to claim 5, this claim as amended includes the elements of a plurality of particles comprising at least thirty five percent by weight of the composition. McAtee does not teach or suggest the use of a plurality of abrasive particles that are at least thirty five percent by weight of the composition. Rather, McAtee teaches that insoluble particles comprise from about "about 0.1 percent to about 20 percent" of a composition. Therefore, McAtee does not teach or suggest each

of the elements of claim 5. Accordingly, reconsideration and withdrawal of the anticipation obviousness rejection of claim 5 are requested.

In regard to claim 7, this claim depends from independent claim 5 and incorporates the limitations thereof. Thus, at least for the reasons mentioned above in regard to independent claim 7, this claim is not obvious over McAtee. Accordingly, reconsideration and withdrawal of the anticipation and obviousness rejection of claim 7 are requested.

III. New Claims

In regard to claim 23, this claim depends from independent claim 1 and incorporates the limitations thereof. Thus, at least for the reasons mentioned above in regard to independent claim 1, claim 23 is not anticipated or obvious over the cited references. Accordingly, Applicant believes that claim 23 is in condition for allowance.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending, namely claims 1-3, 5, 7, 21, 22 and 23 patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 207 3800.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: 9/13, 2004

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Lillian E. Rodriguez 9-13-04
Lillian E. Rodriguez September 13, 2004



Our Ref. No.: 5309P001X

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Dean L. Rhoades

Application No.: 09/802,425

Filed: March 9, 2001

For: COMPOSITION, APPARATUS AND
METHOD FOR SKIN REJUVENATION

Examiner: Frank I. Choi

Art Unit: 1616

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION PURSUANT TO 37 C.F.R. § 1.131

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Dean L. Rhoades, hereby declare that:

1. I am a citizen of the United States of America.
2. I currently reside at 2075 N. Beverly Drive, Beverly Hills, California 90210.
3. I am the inventor of the above-identified patent application.
7. I have reviewed U.S. Patent No. 6,290,976 issued to Messenger (the "Messenger" patent) which was filed on April 6, 2000 and Patent Application Publication No. US 2002/0090385 filed by Fox et al (the "Fox" publication) which was based on a provisional application 60/239,059 filed on October 5, 2000. The Examiner has cited the Messenger patent and Fox publication against the claims of the above-identified application.

8. The invention disclosed and claimed in the above-identified patent application was reduced to practice in the United States of America at least as early as September 15, 1998, as evidenced by the attached documents which are printouts of two formulations (Exhibit A and B). Exhibit A is a formulation of a creme base having moisturizer ingredients that are twenty percent by weight of the base. Exhibit B is a formulation of a composition with the creme base of Exhibit A and aluminum oxide with a particle size of 120 microns. These documents demonstrate the reduction to practice of the invention prior to the earliest priority date of Messenger and Fox.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Respectfully submitted,

Dated: 9-7-04


Dean L. Rhoades



MOHSENI CONSULTANTS

PRODUCT: Microderm Abrasion Cream base

FORMULA : #980910

DATE: 9/15/1998

NO	%	DESCRIPTION	GRAM	POUND	INTL
1	63.432	DI WATER			
2	0.30	50% PANTHENOL			
3	2.00	PROPYLENE GLYCOL			
4	0.20	METHYLPARABEN			
5	5.00	DEHYHAG WAX			
6	8.00	LIPONATE CG			
7	6.00	SAFFLOWER OIL			
8	7.00	OCTYL PALMITATE			
9	0.10	PROPYLPARABEN			
10	0.05	ASCORBYL PALMITATE			
11	.050	LECITHIN			
12	3.50	STEARIC ACID			
13	0.20	CETYL ALCOHOL			
14	2.00	WHEAT GERM OIL			
15	0.10	VITAMIN E ACETATE			
16	0.01	VITAMIN A			
17	.050	CAROT EXTRACT			
18	.010	WHEAT GERM EXTRACT			
19	0.500	PHENPTYETHANOL			
20	0.380	AMP 95			
21	0.800	LUMINESSENSE236-270			
22	0.001	2%BETA CAROTENE			
23	0.144	FDC YELLOW 5 1%			
24	0.173	FD yellow 6 1%			



MOHSENI CONSULTANTS
PRODUCT: Microdermabrasion Cream
FORMULA : # 980911
DATE : 9/15/1998

NO	%	DESCRIPTION	GRAM	POUND	INTL
1	50.0	MICRDERMABRASION CREAM BASE FORMULA # 980910			
2	50.0	WHITE ALUMINUM OXIDE 120			
3					
4					
5					
6					
7					
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VISCOSITY

Viscosity is the measurement of a fluid's internal resistance to flow. This is typically designated in units of centipoise or poise but can be expressed in other acceptable measurements as well. Some conversion factors are as follows:

100 Centipoise = 1 Poise
1 Centipoise = 1 mPa s (Millipascal Second)
1 Poise = 0.1 Pa s (Pascal Second)
Centipoise = Centistoke x Density

■ **Metering Pump Technology**
Fixed- & Variable-Ratio Designs
Mixer Technology
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Material Feed Systems

■ **P-200 Throughput Calculator**
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Application Data & Calculations

■ **Abbreviations & Symbols**
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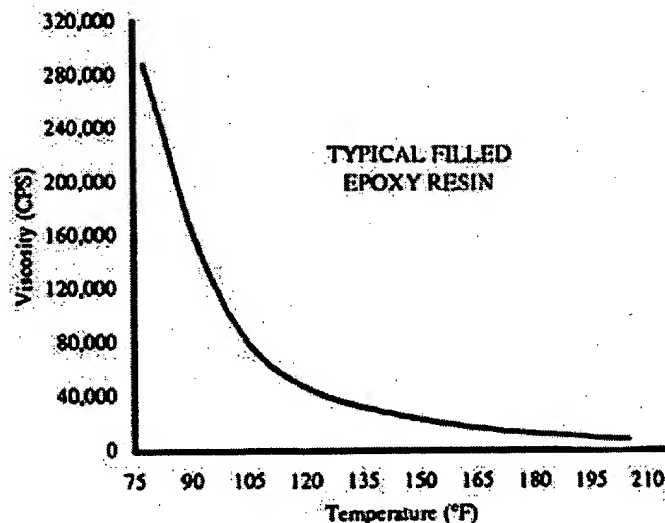
Newtonian materials are referred to as true liquids since their viscosity or consistency is not affected by shear such as agitation or pumping at a constant temperature. Water and oils are examples of Newtonian liquids.

Thixotropic materials reduce their viscosity as agitation or pressure is increased at a constant temperature. Ketchup and mayonnaise are examples of thixotropic materials. They appear thick or viscous but actually pump quite easily.

Paste viscosity is a vague term the viscosity of many materials but needs further definition to design a machine. Some paste viscosity materials will seek their own level or flow slowly and the shorter the time it takes, the easier they are to pump. Others do not seek their own level or flow at all and require pressure to move them from the supply container (cartridges, pails or drums) to the metering pump. These materials require special consideration regarding their feeding into metering pumps to assure the metering pump does not cavitate or to prevent air from being introduced into the material.

One way to differentiate between easy and difficult to flow pastes is to obtain Brookfield viscosities using the same spindle at two different rotational speeds, usually a tenfold difference (e.g. 1 RPM and 10 RPM). This will provide a "thixotropic index" for the particular material. The higher the difference in viscosity at the two speeds, the more thixotropic the material is and easier to pump.

To reduce the viscosity of paste materials to allow easier pumping, heat is often applied. The following graph illustrates how a typical filled epoxy resin reduces in viscosity as it is heated.



Solid materials at room temperature that are designed to be melted to allow pumping require heating above their melt point before they become a liquid. Maintaining heat on this material throughout the metering system (feed tank, pump, material supply hose, mixer, etc.) is normally critical to preventing this material from resolidifying somewhere in the system. A heated cabinet that encapsulates all wetted components of the machine is typically employed instead of just heat blanketing the various components.

Typically, the closer the "A" and "B" materials are in viscosity, the easier they will be to mix. The most difficult materials will have a high viscosity "taffy-like" consistency for one-component with a water thin viscosity as the other component.

Approximate Viscosities of Common Materials (At Room Temperature-70°F)	
Material	Viscosity in Centipoise
Water	1 cps
Milk	3 cps
SAE 10 Motor Oil	85-140 cps
SAE 20 Motor Oil	140-420 cps
SAE 30 Motor Oil	420-650 cps
SAE 40 Motor Oil	650-900 cps
Castrol Oil	1,000 cps
Karo Syrup	5,000 cps
Honey	10,000 cps
Chocolate	25,000 cps
Ketchup	50,000 cps
Mustard	70,000 cps
Sour Cream	100,000 cps
Peanut Butter	250,000 cps

Viscosity Conversion Chart

The following viscosities are based on materials with a specific gravity of one.

Centipoise (CPS) or Millipascal (mPas)	Poise (P)	Centistokes (CKS)	Stokes (S)	Saybolt Universal (SSU)
1	0.01	1	0.01	31
2	0.02	2	0.02	34
4	0.04	4	0.04	38
7	0.07	7	0.07	47
10	0.1	10	0.1	60
15	0.15	15	0.15	80
20	0.2	20	0.2	100
25	0.24	25	0.24	130
30	0.3	30	0.3	160
40	0.4	40	0.4	210
50	0.5	50	0.5	260
60	0.6	60	0.6	320
70	0.7	70	0.7	370
80	0.8	80	0.8	430
90	0.9	90	0.9	480
100	1	100	1	530
120	1.2	120	1.2	580
140	1.4	140	1.4	690
160	1.6	160	1.6	790
180	1.8	180	1.8	900
200	2	200	2	1000
220	2.2	220	2.2	1100
240	2.4	240	2.4	1200
260	2.6	260	2.6	1280
280	2.8	280	2.8	1380
300	3	300	3	1475
320	3.2	320	3.2	1530
340	3.4	340	3.4	1630

360	3.6	360	3.6	1730
380	3.8	380	3.8	1850
400	4	400	4	1950
420	4.2	420	4.2	2050
440	4.4	440	4.4	2160
460	4.6	460	4.6	2270
480	4.8	480	4.8	2380
500	5	500	5	2480
550	5.5	550	5.5	2660
600	6	600	6	2900
700	7	700	7	3380
800	8	800	8	3880
900	9	900	9	4300
1000	10	1000	10	4600
1100	11	1100	11	5200
1200	12	1200	12	5620
1300	13	1300	13	6100
1400	14	1400	14	6480
1500	15	1500	15	7000
1600	16	1600	16	7500
1700	17	1700	17	8000
1800	18	1800	18	8500
1900	19	1900	19	9000
2000	20	2000	20	9400
2100	21	2100	21	9850
2200	22	2200	22	10300
2300	23	2300	23	10750
2400	24	2400	24	11200
2500	25	2500	25	11600
3000	30	3000	30	14500
3500	35	3500	35	16500
4000	40	4000	40	18500
4500	45	4500	45	21000
5000	50	5000	50	23500
5500	55	5500	55	26000
6000	60	6000	60	28000
6500	65	6500	65	30000
7000	70	7000	70	32500
7500	75	7500	75	35000
8000	80	8000	80	37000
8500	85	8500	85	39500
9000	90	9000	90	41080
9500	95	9500	95	43000
15000	150	15000	150	69400
20000	200	20000	200	92500
30000	300	30000	300	138500
40000	400	40000	400	185000
50000	500	50000	500	231000
60000	600	60000	600	277500
70000	700	70000	700	323500
80000	800	80000	800	370000
90000	900	90000	900	415500
100000	1000	100000	1000	462000
125000	1250	125000	1250	578000

150000	1500	150000	1500	694000
175000	1750	175000	1750	810000
200000	2000	200000	2000	925000

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Topical Drug Bioequivalence: FDA Revised Strategy To Be Presented To Committee; Reporting CMC Changes Also On Agenda

FDA will present its proposed "future direction" for ensuring therapeutic equivalence of topical drug products to the Pharmaceutical Science Advisory Committee during a March 12 meeting.

In response to concerns about use of dermatopharmacokinetics, or skin stripping, to determine bioequivalence that were raised by committee members at a Nov. 29, 2001 meeting, FDA withdrew its draft guidance on DPK. The agency said it now plans to take a "fresh look" at the best methods to determine bioequivalence of generic topical dermatologic products.

The committee will be asked to comment of FDA's "current proposed direction" and whether other alternatives should be considered. The agency noted, however, that this meeting is primarily to make the committee aware of the issue and that in depth discussions will take place at future meetings.

FDA will also present its proposed system for classifying topical drug products. The committee will be asked for its input on the proposed nomenclature.

For example, the committee will be asked whether it is "reasonable" to distinguish lotion from cream on the basis of viscosity. Under the agency's proposed definitions, a lotion contains >50% volatiles (as measured by loss on drying) and has a viscosity of <30,000 cps, while a cream has a viscosity >30,000 cps.

FDA would like input on whether there is any value to including attributes such as greasy, non-greasy or cooling in the definitions. Other questions include whether it is worthwhile to draw a distinction between hydrophilic and lipophilic creams and whether the presence of an emulsifier in a formulation should preclude a dosage form from being classified as a gel.

The agency will also update the committee on the use of comparability protocols for post-approval changes in manufacturing processes. FDA issued a draft guidance on the subject in February.

On March 13 the committee will hear an overview on the Office of Pharmaceutical Science's research capabilities, discuss a proposal for parametric tolerance interval testing of aerosol products, and hear an overview on the evaluation of bioavailability and bioequivalence of endogenous drug products.

To watch a live or archived webcast of this meeting, click the button below. To arrange for live videoconferencing or to order videotapes and CDs, email webcasthelp@elsevier.com or call 800-332-1370 ext. 7210.

Posted: Monday, March 10, 2003

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This meeting will be held **March 12, 2003 at the Advisory Committee Conference Room, Center for Drug Evaluation & Research, 5630 Fishers Lane in Rockville, Md. beginning at 8:30 a.m.**

Agenda

Briefing Information

Committee Information

Questions

RELATED STORIES

- Topical Dermatological Drugs Bioequivalence Methods To Be Topic Of March 12 Meeting [Posted: 1/13/03]
- Topical Drug Nomenclature Being Redefined By FDA [Posted: 3/12/03]



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